

Guidelines

- The normal ovary in fertile-age women is up to 4 cm in diameter. The normal uterus is about 7 cm in length and 6 cm wide.
- An enlarged ovary, especially if soft or cystic, is usually because of a functional or
 physiological cyst. Ovulating women make follicular cysts early in their cycle and then midcycle, ovulate, and later in the cycle and up to the first few days of the menses, a corpus
 luteum cyst can often be palpated or seen by ultrasound.
- Cysts are found in over 50% of menstruating age women by ultrasound and if small and asymptomatic, they are usually of no clinical significance. Small functional cysts may even be seen by ultrasound in postmenopausal women.
- Cysts or enlargements early in pregnancy are usually the corpus luteum, which is necessary to maintain the pregnancy up to about 10 weeks.
- Cysts over 8 cm are frequently pathological, however, there are some functional cysts 6 to 8 cm in diameter which resolve by the next cycle.
- Mild uterine enlargement is normal after pregnancies. Confirm the enlargement is symmetric
 and stable by re-examining in 3 to 6 months and if still concerned, refer for evaluation and
 imaging.
- If the woman is prepubertal, postmenopausal, or if the client has been on birth control pills or DMPA injections for over 6 months, or if the enlargement is bilateral, then the enlargement is usually not due to a functional ovarian cyst. These adnexal masses should probably be referred for evaluation and imaging.

Examination

The standard medical history is reviewed and enlarged upon as necessary. Document if there is a family history of adenocarcinomas like breast, colon, or ovarian in first degree relatives. If indicated, perform HCG testing and STD testing. Obtain outside records if a prior history of ovarian or uterine enlargement on exam or ultrasound.

Management

- Rule out pregnancy. If the woman is not pregnant, three cycles of pills may be given to be started on the first day of her menstrual cycle. OCPs and DMPA will suppress ovulation and can prevent future cysts. If enlargement persists on pelvic exam after 6 to 8 weeks, refer the client to a gynecology clinic. She would then need ultrasound imaging and that should not be ordered by the Family Planning Program as we do not do the surgery or manage persistent adnexal masses.
- If the woman is pregnant, note the enlargement on the verification of pregnancy form given to the client for her clinician. Explain the signs of ectopic pregnancy if the client has risk factors like prior ectopic or infertility treatment. Refer emergently if the client is having bleeding or pain. Refer for abortion or pregnancy care as desired, but have her inform the clinician of the "cyst" when making her appointment. Reexamine the woman after termination of pregnancy, and if the cyst persists, refer for evaluation and imaging.

- If the mass is solid or is a cystic mass larger than 8 cm, do not follow and refer immediately (next available appointment) for evaluation, gynecologic work-up for possible surgery, and the referring facility should order the imaging studies, not the family planning program.
- If the records report uterine fibroids were diagnosed, then these are almost always benign. The size of the fibroids needs to be checked in 6 months from initial diagnosis and then every year to make sure there is no rapid enlargement. OCPs and DMPA are okay to prescribe. If the woman develops irregular bleeding not controlled with cyclic OCPs or rapid uterine size enlargement, then she needs to be referred for evaluation and possible surgical treatment.
- If a family history indicates there could be a familial tendency for ovarian cancer, refer the client for screening and possible genetic testing (206-616-2135 is a UW referral). All American women have a 1% lifetime risk of ovarian cancer. Women with 1 first degree relative have an increased lifetime risk of about 6% and with 2 first degree relatives the risk can be as high as 40% if the woman carries the same gene as her relatives. Sometimes women with these genes will choose to have prophylactic ovarian removal. There is evidence that the use of OCPs can prevent not only sporadic but also hereditary ovarian cancers. Use of OCPs and probably DMPA for 5 to 10 years, because of the progestin effect and ovulation suppression can decrease a woman's lifetime risk of ovarian cancer 50 to 80%.



Definitions

- Primary amenorrhea is when a 16-year-old has never had a menses. The Family
 Planning Program should not be working up primary amenorrhea. These girls should be
 referred.
- **Secondary amenorrhea** is when there has been no menses for six months in a woman with menses in the past.

History and Examination

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The physical examination is performed to evaluate breast and pubic hair development. A urine test for pregnancy and a cervical smear for fern test documenting estrogen production may be performed in the clinic. HCG testing should always be considered. Consider referral for a prolactin test if there is long-term amenorrhea especially with galactorrhea. A level of >100mg/dL suggests a prolactinoma. A TSH could also be done if the prolactin is elevated or if there are signs or symptoms of thyroid disorders.

Treatments

It really depends on what the woman desires, if she is seeking pregnancy the plan will be very different from a woman wanting contraception.

Medroxyprogesterone may be used to induce menses when there is amenorrhea due to anovulation. Provera provides the progesterone stimulus to the estrogen-primed endometrium to begin a menses as the progestin is withdrawn. Provera will not stimulate a menses in a woman with little estrogen production.

Indications for Medroxyprogesterone

- Postpill or post partum amenorrhea of over eight weeks duration, where menses are desired.
- Postpill or other amenorrhea of six months are more to demonstrate intact hypothalamicpituitary-ovarian uterine system.
- If DMPA injection use in the past, do not expect oral provera to always trigger a menses until 6 to 12 months after the last injection since estrogen production could still be suppressed.
- Secondary amenorrhea when pregnancy has been ruled out.
- If a client with secondary amenorrhea is seeking contraception, COC pills can also be given as a non-routine OCP start if strongly suspected oligovulation is the etiology. There is no reason to prove it and sometimes a provera withdrawal may trigger an ovulation and the client then experiences an unwanted pregnancy.

Precautions for Medroxyprogesterone

- Known pregnancy although it DOES NOT cause birth defects;
- Tumors of breasts or reproductive organs;
- The dose used will not prevent pregnancy.

To Prescribe Medroxyprogesterone Withdrawal Document

- Negative sensitive urine test (25mIU) for pregnancy.
- Normal pelvic exam in the past 12 months.
- Client is aware this is not a contraceptive method and she can still get pregnant.

Prescribing Medroxyprogesterone

Prescribe medroxyprogesterone 10 mg one daily for 10 days and counsel the client to expect menses after the pills have been taken. Teach client to use the <u>Menstrual Calendar Reminder Card</u> to document her cycles.

Follow-up

- An appointment should be made in two to three weeks after taking the medroxyprogesterone pills.
- If menses has occurred, this rules out hypothalamic or pituitary problems. Birth control may be instituted as desired by the client. No further testing is necessary.
- Birth control could have been started for the client without a provera withdrawal if pregnancy is not being sought, secondary amenorrhea less than 12 months, and no signs or symptoms indicative of hypothalamic or pituitary dysfunction.
- If menses has not occurred after provera, a urine test for pregnancy and a pelvic examination if not already done should be done. If these are negative and the amenorrhea has been for more than six months duration in a woman who is not nursing and is under 40 years of age, consider referral for endocrine evaluation to assess for premature ovarian failure or other endocrine disorder.



Definitions

Androgen disorders are very common. They occur in about 10% to 22% of women and usually start during puberty. Many of the women consider themselves to be normal but some may have polycystic ovary syndrome (PCOS) or hirsutism.

Women with androgen disorders frequently present with gynecological problems including menstrual irregularity, dysfunctional uterine bleeding, amenorrhea, infertility, ovarian enlargement or frequent ovarian cysts, endometrial hyperplasia, fibrocystic breasts, or even virilization.

Dermatological manifestations include acne, especially if it is severe or cystic, oily skin, hirsutism, alopecia, seborrhea, hidradenitis suppurativa, and acanthosis nigricans. Many women shave or mask hair or skin changes and must be specifically asked about these conditions.

Congenital adrenal hyperplasia (CAH) occurs in 1/14,000 women but is more common in Ashkenazi Jews, Alaskan Eskimos, Latinos, and Yugoslavians. Consider androgen disorders in women with a large variety of presenting signs and symptoms. Any woman whose menstrual cycle varies by more than 5 days each month should be considered as possibly having an androgen disorder. Women with infertility should be referred to evaluate for adult and irregular menstrual cycle onset CAH which can reduce fertility.

Medical manifestations include the metabolic syndrome manifested by android obesity, elevated blood pressure, insulin resistance, adrenal hyperplasia, and lipid abnormalities including elevated triglycerides and decreased HDL. Divide the circumference of the waist by the circumference of the hips and if the ratio is greater than 0.85, this is the definition of android obesity and it increases the risk of long term complications and morbidity and mortality. Many women can later develop diabetes and should be screened.

Long term risks from androgen disorders include hypertension, diabetes mellitus, cardiovascular disease, endometrial cancer, ovarian cancer, and possibly breast cancer, thus the need to identify these women and prevent the consequences when possible is important.

Evaluation

Management can frequently be based upon clinical diagnosis without any laboratory testing. Endocrine tests are expensive, sometimes not diagnostic, and vary because of cyclic or diurnal changes. Assessment of hirsutism can be done with the <u>Hirsutism Classification Chart</u>. It is prudent to do glucose screening and lipid screening for all women over 35 with androgen disorders. Consider an HCG for amenorrhea, a hemoglobin or hematocrit for bleeding problems, and an endometrial biopsy referral in high risk women over 35 with a worrisome bleeding pattern because endometrial cancer is common with prolonged PCOS not treated with progestins.

Most women with androgen disorders do not need special endocrine tests. These should be ordered in consultation with the Family Planning Medical Director. Androgen evaluation to rule

out the very rare cases of tumors is indicated for rapid onset of hirsutism and virilization (enlarged clitoris, deepened voice, or male pattern balding). Free or total testosterone levels frequently are elevated in all androgen disorders. However, free testosterone is normal in about one-third of women with androgen disorders. Levels of testosterone well in excess of 200 mg/dL could suggest an ovarian or adrenal tumor. High levels of DHEA-S (dehydroepiandrosterone sulfate) indicate an adrenal problem and if well in excess of 700 micrograms/dL, could suggest an adrenal tumor. In PCOS the LH is typically higher than the FSH but this is highly variable and not the only result needed for diagnosis.

Treatment

If there is amenorrhea, do a withdrawal test with medroxyprogesterone acetate (Provera). If there is no bleeding, refer for endocrinological evaluation. All women with androgen disorders who are not actively seeking pregnancy should be strongly encouraged to use a combination oral contraceptive pill from puberty to menopause, except for intervals related to pregnancy. This will suppress the androgen production and relieve or treat many of the associated problems. Results often take four to six months to be noticeable to the client. Estrogen can help prevent more hair growth but it will not get rid of existing hair. These women are at especially high risk for cancer of the endometrium and cancer of the ovary and the cancer risks can be decreased 50% to 80% in these women with COC pill use.

Advise the woman to avoid drugs that can cause androgen effects including minoxidil, diazoxide, phenytoin, phenothiazines, androgenic progestins, glucocorticoids, cyclosporine, danazol, streptomycin sulfate, and anabolic steroids. An anti-androgen, Spironolactone, can be helpful in preventing further hair growth especially if used with an estrogen-containing pill like Ovcon 35. It can be prescribed in doses of 25 to 100 mg once to three times a day with the maximum daily dose of 300 mg. It is best to begin slowly. If you have never prescribed it before, consult pharmacy or other resources. Spironolactone is a diuretic, anti-hypertensive agent and long-term use of this product should involve potassium monitoring and because is it a possible teratogen it is important to use this only with an effective contraceptive.

Recommend the use of local measures for acne such as benzyl peroxide, antibacterials and retinoic acid (see <u>Acne Handout</u>). Hirsutism can be managed temporarily with plucking, bleaching, or shaving and permanently with electrolysis or laser hair removal. Topical 13.9% eflorithine hydrochloride (Vaniga ™) may also help to remove unwanted facial hair growth.

When pregnancy is desired, many women with androgen disorders may have infertility problems related to oligoovulation; research has found if obese women lose 10 to 15% of their body weight, normal ovulation can often return. If the <u>Basal Body Temperature Chart</u> indicates anovulation, referral to an infertility clinic is indicated.

Breast Problems

History

The standard medical history is reviewed for a history of breast cancer in first degree relatives (mother, sister, daughter, or even father's sister if age <50 when diagnosed with the cancer). If more than one first degree relative with breast, ovarian, or colon cancer, especially if at an early age at diagnosis, then counsel client to seek genetic testing and advise about possible increased cancer risk and need for early screening. If breast cancer was diagnosed in a first degree relative, then the woman should be advised to begin mammogram screening 10 years prior to the age of the relative's diagnosis of cancer.

Examination

Complete breast examination is performed and results documented. Breast self-examination technique should be reviewed.

Management

Cyclic Mastalgia: Often inappropriately called "Fibrocystic Breasts" - these women often have tender or nodular feeling breasts. Explain and reassure the woman. Advise reduction in caffeine products and 400 mg of Vitamin E daily can help. If the client has specific concerns or abnormal findings, then referral to a breast specialist is indicated. One of the biggest causes of malpractice suits is a delay in the diagnosis for women with breast cancer. Therefore, any client that continues to have breast pain complaints needs a specialist evaluation and possibly imaging.

Nipple Rash: Suspect contact allergic reaction. Have client use cotton bras. Avoid soaps, cosmetics, lotions, etc. If macerated, use soaks. If eczematoid, use hydrocortisone cream 1% applied lightly qid. If persists, refer to breast specialist, especially in women over age 35, where Paget's disease with cancer should be considered.

Nipple Discharge:

- Milky discharge or Galactorrhea is significant only if spontaneous (without expressing the breast). Can be unilateral or bilateral. Galactorrhea is a common side effect of hormonal contraception. Confirm fat globules present by examining the fluid under a coverslip and low power. Confirm no visual field loss or new, worsening headaches, which would possibly signal an enlarging pituitary adenoma. Outline the role of breast stimulation, hormones (OCP and DMPA), marijuana, tranquilizers, tricyclic antidepressants, narcotics, Aldomet, reserpine, and many other medications that change estrogen/progesterone levels.
 - If the woman is <u>trying to get pregnant</u>, no contraceptives for one year, no pregnancy, and definitely no hormonal contraceptives should be used for 6 months if OCP use history and 12 months if DMPA past use. Consider referral as sometimes small elevations in prolactin can reduce ovulation. There are medications that can reduce the production of prolactin.

- If the woman is <u>using contraception with regular menses</u>, then counsel about common causes of galactorrhea and plan recheck in six months and if persists, refer to primary care provider.
- If the woman experiences <u>amenorrhea for 6 or more months</u>, refer her to a primary care provider or, if not possible to refer, check PRL and TSH. Refer to an endocrine clinic for imaging if the prolactin is greater than 50, although usually no imaging or treatment is needed unless the prolactin level is greater than 100.
- Sticky, green or blue colored, or grumous discharge is usually due to benign ductal
 ectasia. The woman may have periareolar pain, itching, or occasionally erythema. Do a
 guaiac test to rule out presence of blood. Management is hygiene, avoidance of
 manipulation, and reassurance.
- Watery, bloody, serosanguinous or serous discharge may be due to a benign condition but is also suggestive of cancer. Confirm the lack of fat globules under microscopy and giauac the fluid. Often the woman needs mammography or surgical exploration of the duct. Refer to breast specialist or primary care physician. DO NOT send cytology of the fluid as that is best done at the referral clinic and the results may be misleading.

Patient Complaint or Exam Finding of Possible Breast Mass

Evaluate and record exam findings carefully on the chart. If the area of concern is cystic, soft, irregular and not a discreet mass, schedule the client for a revisit within 6 weeks or at a different point of the menstrual cycle and if concern persists, refer to a breast specialist. If the mass is fibrous, very firm, and discreet, or if the client found the mass and the provider can also palpate the mass, then the client warrants a referral to a breast specialist or to her primary care physician for diagnosis. Imaging should not be ordered without this consultation as there can be a 10% false negative rate with mammograms and sometimes ultrasound instead of mammography would be ordered and the imaging should be ordered by the specialty clinic so they have access to the images. It is usually not necessary to withhold hormonal contraceptives during this time of evaluation, it would be worse if the client become pregnant and use of OCP or DMPA has not been shown to worsen the prognosis. If the mass is diagnosed to be of benign etiology, then continue to follow the client with annual exams, carefully documenting the size and prompt referral back to the specialty clinic if there are changes or persistent patient complaints.

Screening Mammograms

Screening mammograms may be recommended every year in women over age 40, according to the ACS and ACOG, although an NCI panel recommended not beginning until age 50 with annual screening. Studies show routine screening mammograms on women under the age of 50 yield too many false positives to be cost effective. If a woman under 50 is to get a mammogram, it should be in the first two weeks of her menstrual cycle to improve the images (more false positive studies if done in last two weeks of menstrual cycle). In women with a family history of breast cancer in a first degree relative, screening mammograms should begin 10 years before age of diagnosis of cancer in their relative. In addition, women with early breast, colon, or ovary cancers in other family members may benefit from genetic screening with a breast specialist. Additional risk factors for breast cancer include obesity, daily alcohol use, high fat dietary intake, and lack of term pregnancy and/or lactation history. Perhaps when counseling women between the ages of 40 and 50 about mammography, a woman could be told of the controversy about the benefits and possible lack of benefit when screening before 50 but then decide based on her own perception of her risks.

Breast Cancer Risk Estimates

Reprinted below is a table from an article on breast cancer risk assessment for women with a family history of breast cancer (JAMA; 273:577-85).

Table 1. – Breast Cancer Risk Estimates for Members of Moderate-Risk Families*

Affected Relative Age of Affected Relative,		Cumulative Breast Cancer Risk by Age 80, %	
	У		
One first degree	<50	13-21	
_	≥50	9-11	
One second	<50	10-14	
degree	≥50	8-9	
Two first degree	Both <50	35-48	
-	Both ≥50	11-24	
Two second	Both <50	21-26	
degree [†]	Both ≥50	9-16	

^{*} Adapted from Claus et al. Risk estimates are derived by including age extremes from the risk tables calculated by Claus. For example, for affected relatives younger than 50 y, the lower limit is the calculated risk if the affected relative is in the 40- to 49-y age group and the upper limit is the calculated risk for a relative in the 20- to 29-y age group. Thus, these figures represent the range of risk based on age and are not confidence intervals.

This table was published by the <u>Susan G Komen Breast Cancer Foundation</u> regarding the overall risk for all American women with no known family history.

What Is Your Risk of Developing Breast Cancer?

By age 25	one in 19, 608	By age 60	one in 24
By age 30	one in 2, 525	By age 65	one in 17
By age 35	one in 622	By age 70	one in 14
By age 40	one in 217	By age 75	one in 11
By age 45	one in 93	By age 80	one in 10
By age 50	one in 50	By age 85	one in 9
By age 55	one in 33	Ever	one in 8

Avoid Malpractice

Failing to diagnose breast cancer is the number one cause of malpractice suits. The most frequently cited reasons for this failure in an article (1995 OBG Management) were:

- Physical findings failed to impress physician (169 of 487 malpractice suits)
- Failure to follow up with patient (150)
- Negative mammogram report (125)
- Mammogram misread (110)
- Failure to do proper biopsy (110)
- Delay in or failure to consult (75)
- Failure to react to mammogram (60)
- Distracted by other health problems (55)
- Repeat exams did not arouse suspicion (55)
- Failure to order mammogram (54)

Both paternal or both maternal

Cervical Cancer Screening

Overview

Screening for early detection of cervical cancer and precancerous conditions of the cervix has been done by the "Pap Test". Papanicolaou testing, microscopic examination of exfoliated cervical cells, began in 1943 as a method to detect pre-invasive cervical cancer. Worldwide, more women die of cervical cancer than any other gynecologic cancer. In the United States deaths from cervical cancer dramatically dropped with pap test screening. Most women diagnosed with cervical cancer have either never had a pap test or have had very infrequent screening – (no test for 10 years).

It has now been shown that the HPV, Human Papilloma Virus, is the etiologic agent that begins the oncogenic changes resulting in most squamous cell cervical cancers which account for 85% of the cervical cancers. About 10 to 15% of cervical cancers are adenocarcinomas. Adenocarcinomas are also caused by HPV viruses, grow very rapidly, 20% of cases had a negative pap test within the past year, and there is a possible association with long term COC pill use. Neither form of cervical cancer has been proven to "run in families" or to be hereditary although there is beginning to be evidence our immune systems, which are inherited, may respond differently. Recently the new Bethesda System was introduced 9/01 updating the 1991 nomenclature and classification of cytology (www.bethesda2001.cancer.gov).

Who to Test

Because cervical dysplasia and cancer risk are linked to sexual acquisition of HPV, annual pap testing should begin 3 years after becoming sexually active or by the age of 21 and continue until age 30 (January 2003 U.S. Preventative Services Task Force guidelines implemented 4/2004). HPV infection is the inciting event for cervical cancer but it takes time to develop and for this reason invasive cancer is virtually unheard of in adolescents. The published data on the natural history of HPV infection, and low-grade and high-grade precancerous lesions suggest there is little risk of missing an important cervical lesion within 3 years of the initial exposure to HPV. In young women aged 13 to 22, 70% of high-risk and over 90% of low-risk HPV infections regress within 3 years. Screening before the 3 year period, therefore, may lead to an overdiagnosis of clinically insignificant lesions and unnecessary treatment (CA Cancer J Clin 2002; 52: 342-362 American Cancer Society guidelines for the early detection of cervical neoplasia and cancer).

After age 30 if all pap testing has been negative, then pap testing can be less frequent in low risk women. Because there is a false negative rate of 3 to 10% with smear cytology tests there should be three sequential annual tests to establish 100% normal cytology before reducing the frequency at age 30. Low risk asymptomatic women (only one lifetime sexual partner, or the same partner for enough years to insure no HPV infection, no HIV infection or immunocompromise, and all prior normal pap test results) pap tests could be done only every 2-3 years after the initial three annual tests are negative even with hormonal contraceptive use in women over 30. Just because the decision to not provide cytology screening is made, a pelvic examination should still be a part of an annual gynecologic examination and according to the ACOG guidelines it is recommended to screen for vulva, uterine, or other pelvic abnormalities by physical examination.

If the client is using a hormonal contraception even if only for dysmenorrhea, she will need to begin

cervical cytology screening at age 21. There is an epidemiological association between long-term COC pill use and cervical cancer and part of monitoring a hormonal prescription is to perform cervical cytology at regular intervals. She may choose to sign the Birth Control Method Specific Informed Consent Form and using the Delayed Pelvic Guidelines to document the reasons for the exam refusal and of her understanding that she may have early pre-cancer of the cervix, which, if diagnosed early, could prevent hysterectomy and death.

Established clients with a documented normal pap from up to 12 months prior may delay their annual exams and pap test up to 6 months provided there are no concerns or problems and there is documentation why the client is choosing to delay her pap test. After 18 months the client can no longer be given hormonal contraceptives without an annual exam unless she signs the <u>Birth Control Method Specific Informed Consent Form</u> with documentation of understanding that she may have early pre-cancer of the cervix, which if diagnosed early, could prevent hysterectomy and death.

New clients may choose to delay their pap test screening for six months and will still be given hormonal contraceptives, however, the <u>Delayed Pelvic Guidelines</u> must be followed. The transfer client guidelines may allow a new client to receive hormonal contraceptive methods until the 12 month interval between annual exams has been reached and it could be stretched to 18 months, if the prior cytology report was a documented normal result and there is charting that client is choosing to delay her pap test.

At **age 65** if the client has a documented history of repeated negative pap tests and no history of dysplasia then cytology testing may be discontinued, but annual pelvic examination is still beneficial to evaluate the rest of the genital and pelvic examination.

A woman with a documented **history of hysterectomy** for benign reasons (fibroids, bleeding, endometriosis, or pelvic pain for example) and no history of cervical dysplasia has almost no risk of cervical cancer, therefore cytology is not necessary or only performed every 10 years after an initial post-operative vaginal cuff pap at one year. Confirm the client had a complete and not a supracervical hysterectomy. A supracervical hysterectomy leaves the cervix and requires ongoing cervical cancer screening. If the hysterectomy was done for cancer, consult with the Family Planning Medical Director because the client may need her follow up exams with a cancer specialist.

Any **premenopausa**l woman with complaints of **spotting between menses or with intercourse**, needs to have a normal pap test documented within the past year. Exclude pregnancy and infection. Treatment with COC pills or cyclic provera should be attempted to regulate the bleeding and if after 3 months the bleeding persists and if there is no other etiology (such as depoprovera or PID) for the complaint, she should be sent for colposcopic exam and/or endometrial biopsy, especially if over the age of 35.

Postmenopausal women not on HRT (hormone replacement therapy) with spotting need gynecologic evaluation. Women with no bleeding for one year prior beginning on HRT can be expected to spot and do not need referral for endometrial biopsy unless still spotting at 6 months of HRT use or if medical history suggests risk factors for endometrial cancer and her prior menstrual history is unclear. Women using HRT need annual pelvic and breast exams just like other women using hormonal medications.

DES (diethyl stillbesterone) was used from 1943 to prevent miscarriage until 1971 when it was banned by the FDA. DES is not a carcinogen but it is a teratogen and when taken while pregnant

the female fetus genital tract can develop abnormally. Structural changes include uterine and cervical malformations and it is estimated about 70% will have an abnormal hysterosalpingogram. All women presenting with a DES history should have the history confirmed if possible, a routine endo/ecto, cervical pap test sampling the visible squamocolumnar junction and a separate 4guadrant vaginal cytologic smear sent, and if they have had no prior colposcopic exam, be referred for a DES specific, complete colposcopic exam of the cervix and vagina. If the exam is abnormal, the client may need treatment and annual colposcopic examination by the referral physician. If this exam and the cytology are normal, the client can be followed with yearly routine ectocervix pap test and an additional 4-quadrant vaginal smear. With the bimanual portion of the annual exam. careful palpation of the vaginal walls is done to make sure there is no nodularity, which could be indicative of early vaginal adenocarcinoma. In-utero under the influence of DES, islets of glandular tissue can be left in the vaginal wall and are usually below the surface epithelium. The risk of this vaginal adenocarcinoma is less than 1 in a thousand. If they become malignant, then sometimes nodules can be palpated and if present on exam (make sure the nodules are not rectal stool), refer the client to a gynecologist as this will be a difficult evaluation. Women can find more information on DES at www.cdc.gov/DES.

When to Test

The best cytologic specimen is obtained after a minimum of 4 weeks since the last cytology sample and 48 hours from intercourse, tampon use, vaginal medication use, or bleeding. If a client is diagnosed with vaginitis or cervicitis it may be best to defer the pap test until these conditions are resolved. The pap test result could be falsely abnormal due to inflammation. Cytology is best done at least 8 weeks after an abortion or pregnancy unless the woman needs screening. Pap testing is appropriate and should be done as needed in pregnancy with both the spatula and cytobrush.

How to Test

Patients can be given a handout on Pap testing prior to tests called: Cervical Cancer Screening Patient Handout. A small amount of water soluble lubricant gel can be placed on the outside inferior blade of the speculum to ease speculum insertion (Obstet Gynecol 2002: 100:887-8). Avoid sampling the lubricant for assessment of vaginal discharge or culture collection. Use a large cotton swab to gently wipe away any excess cervical mucous or discharge, then use the spatula to scrape the ectocervix in a 360 degree arc, for 2 to 3 rotations, being sure to include the squamocolumnar junction in the portion sampled. Next use the cytobrush, insert into the cervical os, and sample with only a 180-degree arc to minimize bleeding. The cytobrush should be used for all pap test collections, even in pregnancy. It is not contraindicated and if not used, the sample is frequently inadequate. Apply both specimens to the glass slide and IMMEDIATELY add alcohol fixative. Use either an alcohol pad or an alcohol spray bottle (which the cytology lab will provide free if requested). The PHSKC system uses smear cytology preparation rather than liquid cytology. If liquid cytology is used then testing intervals should be every 2 – 3 years because of the increased sensitivity and risk of false positive results using liquid cytology. Offer the Pap Reminder Card to all women at the time of pap testing. A woman can refuse if she does not want mail sent to her address. If she agrees, on the day of the pap test have the woman fill out the Pap Reminder Card so it can be sent to her in one year to remind her of her annual exam.

Tracking Specimens

When completing the requisition, indicate to the lab if the client has a history of HPV, cervical dysplasia, or treatment, like LEEP. A detailed chronology of pap result history is unnecessary. The lab requisition form stickers can be placed on the <u>Lab Test Tracking Log</u> as a reference if the lab misplaces the specimen. Use the Lab Test Tracking Log to document the specimen has been sent and a result obtained. The tracking log should be used to verify that results for the test have been obtained in a timely fashion. The tracking log should be kept for three years and then

shredded. When the reports are received they should be signed with a legal signature and dated as received of that date.

Documentation of Cytology Results

We recommend a designated person at each site be responsible for reviewing pap test reports every week. The lab reports should be signed with a legal signature and noted "reviewed", with the date of review on each report. The pap Bethesda diagnosis should be recorded on the Family Planning Flow Sheet to allow a quick review of pap results. Abnormal results need to be reviewed by the provider with a follow up plan documented on the lab report and in the progress note section after consultation with the provider. The provider should be notified of all HGSIL reports, as soon as possible. The Family Planning Medical Director should be contacted about any invasive cancer results. The woman should be notified of any abnormal result after the plan has been discussed with the provider. The contact with the woman can be by letter, in person, or by phone contact. Document in the progress notes and the pap follow up plan how the client was notified. Make three good attempts, use all phone numbers provided and if no phone contact, send a letter using the Abnormal Cytology or Colposcopy Result Letter or Laboratory Result Letter, as appropriate. For pap test results indicating the need for immediate colposcopy, at least three attempts should be made to contact the client, and if she cannot be reached, send a registered letter, if the diagnosis was HGSIL. A public health nurse could be sent to see the patient if the cytology was suggestive of invasive cancer. Do not use card boxes to record contact with a patient that is not also entered into the progress note section of the chart as well.

Use the <u>Abnormal Pap Tracking Alert Slip</u> to flag the chart so at revisits providers are alerted the patient needs pap follow up. Progress note entries should include the patient contact regarding any follow-up plan. Use a tickle reminder system like a calendar with a patient sticker for the call back month to remind the patient of her recommended follow up and document the contact in the progress notes. If she then fails follow-up, document this as well in the progress notes and if staff feel it is necessary a letter can be sent to remind the client using the <u>Reminder Pap Letter</u>.

Interpreting Cytology Results

The laboratory should send a written report within 14 days. Read the Bethesda Diagnostic Descriptive Terms category carefully, to obtain the pap test result. Use the Pap Diagnosis Name Comparison Chart, if needed. Do not use the outdated class system "Epithelial cell abnormality," as it is not the final diagnosis and one must look below to see what exactly is the problem. If there are any conflicting or confusing statements on the pap test report, consult with the Family Planning Medical Director before making a plan for follow-up with the client. Use the following list of categories to help make follow-up, treatment, or referral plans for specific clients as discussed below.

- Negative for Intraepithelial Lesion or Malignancy (NIL) Pap Test Result: This indicates the client has normal cervical cytology and the next pap test is recommended in 12 months. If there have been 3 consecutive NIL results, if the client is >30 years of age, and has no risk factors, then cytology could be obtained every 2 3 years.
- Unsatisfactory Pap Test Result: Repeat when practical, preferably within three months.
 Correct any identified cause of the unsatisfactory pap first. The clinic should carefully look at
 the 6-month statistics for their site to see that their unsatisfactory cytology specimen rate is not
 elevated. If greater than 1.5% of pap test need to be repeated because of unsatisfactory
 collection technique, the cytology lab should be contacted so the site can get a more detailed
 report of what and perhaps who is the source of the problem.

- Benign Cellular Changes (BCC) Pap Test Result: This category is not part of the 2001 Bethesda System but if used it indicates normal cervical cytology and the epithelial cells are normal. However, the following are benign and/or mild inflammatory descriptors, which may necessitate some follow-up depending on the individual client's history. Since BCC is a normal result, the next pap test is in one year.
- Excessive Inflammation, Follicular Lymphocytic Cervicitis: Many women can have cervical
 inflammation or ectopy without an infection and there is no reason to treat unless there is a
 documented infection to treat. At her next visit it may be prudent to evaluate her for a possible
 infection check.
- Candida, Yeast: If not symptomatic, there is absolutely no indication to treat as yeast does not
 cause upper tract disease and is a common finding in the vagina of women especially if
 pregnant or on COC pills.
- Cellular Changes Consistent With Bacterial Vaginosis: Predominance Of Coccobacilli Consistent With Shift In Vaginal Flora (A Sign Of Bacterial Vaginosis): Recommend treatment only if exam findings confirmed pap test (sometimes pap is not accurate) and if the client is symptomatic, pregnant, planning an abortion, or an IUD insertion.
- Actinomyces (IUD associated): Typically actinomyces is not seen until the IUD has been in place for over 6 years. Refer to the IUD guidelines.
- **Trichomonas**: Treat the woman and her contacts. If possible verify by pelvic exam because occasionally the cytology diagnosis is incorrect and what looked like a trich organism was actually a deformed white blood cell. Liquid cytology specimens are more accurate for this diagnosis with a specificity of 99% (Obstet Gynecol 2003; 188:354-6).
- Herpes Simplex Virus: Notify the woman if she has not already been diagnosed in the past.
 HSV epithelial changes seen on the pap test are highly diagnostic and specific for HSV,
 however, it is also reasonable to consult the STD guidelines and provide culture and/or
 serology as indicated by those guidelines.
- Parakeratosis, Hyperkeratosis, and Reactive squamous or endocervical cells are all benign changes. Unless nuclear atypia is described, which should have been signed out by the lab as "ASCUS" and not "BCC", the pap test can be repeated in one year as with other normal pap test results.
- Endometrial Cells present- If the client is still premenopausal then this is a normal finding. If
 the client is postmenopausal, then referral is indicated unless documented normal endometrial
 biopsy in past year and on HRT.
- Endocervical Reserve Cell Hyperplasia-This is benign and no action is needed.
- Absence of Endocervical Cells- If the client has had no previous abnormal paps and
 otherwise satisfactory, repeat in one year. Many women using progestin containing hormonal
 contraceptives may have regression of ectopy and migration of the transformation zone up the
 canal and lack of endocervical cells on the specimen should not be a cause for concern if
 indeed the cervical os was sampled well with the cytobrush. But if the client has a NIL result

but no endocervical cells and a history of high-grade cervical dysplasia treatment, repeat the pap test within 3 months. If still no endocervical cells on repeat, discuss the case with the Family Planning Medical Director as the client may need referral or an endocervical curettage (ECC) particularly if there were positive margins or a positive ECC at the time of treatment. If ECC tissue results are normal, annual pap tests without endocervical cells are acceptable as long as the client has normal cytology and no symptoms like post-coital bleeding, bleeding between menses, or sign of new HPV infection. In postmenopausal women and even long term OCP or DMPA users, many cytology samples will lack endocervical cells and there is no need to do additional testing. Recent studies found that the absence of endocervical cells in untreated women undergoing routine screening was actually predictive of a normal colposcopy exam and the absence of high-grade dysplasia biopsy.

Abnormal Pap Test Results Requiring Follow-Up:

Atypical Squamous Cells Indeterminate for Dysplasia (ASCUS) Low Grade Squamous Intraepithelial Lesions (LSIL or CIN I)

- If the client is 26 years or older referral for colposcopy is indicated. In fact according the
 ASCCP guidelines (JAMA 2002;287:2120) all women with LGSIL and ASCUS (unless a
 negative HPV test has been obtained) should be referred immediately for coloposcopy.
 However given the PHSKC population which is very young and resource limited, observation
 for ASCUS and LGSIL in younger clients can be a choice for some clients as described below.
- If the patient is under age 25 with no prior history of cervical dysplasia and has had normal cytology results in the prior 3 years or has only become sexually active in the prior 3 years then repeat her pap test in 6 months. If the repeat pap test is normal, then repeat pap test in 12 months and consider adjusting the annual exam also to be in 12 months. If the repeat pap test is ASCUS or LGSIL repeat the pap again in 6 months with colposcopy referral only for atypia or LGSIL that persists for 18 months or more. A longitudinal study found 91% of LGSIL lesions regressed within 36 months in women under age 22 at diagnosis and only 3% progressed to HGSIL (Lancet 2004;364:1678-83). A large observational cohort study of the Kaiser population found the cytology rates for CIN II-III are more common in women 25 to 29 years of age and CIN I peaked at ages 20-24 (Am J Obstet Gynecol 2004;191:105-13). It is fairly well accepted that for women under age 22 observation or repeating an ASCUS or LGSIL cytology result is the preferable management thereby utilizing colposcopy only for persistent disease and treatment should not be done for CIN I in this population. In fact, treatment for CIN I-II in young women may also be unnecessary given the high rates of spontaneous regression although concerns about compliance could change this risk-benefit assessment (J Pediatr Adolesc Gynecol 2004;17:303-11). Excisional treatment or LEEP has been associated with an increase in preterm birth; consequently one must balance treatment of a precancerous lesion at a young age against reproductive outcomes (Obstet Gynecol 2005;105:325-32).
- If the client has not had a documented normal cytology result in the past 3 years a colposcopy referral may be considered. Approximately 10% of ASCUS represents HGSIL although only 1% of all ASCUS are CIS; but these rates increase in women not getting regular screening.
- If the last pap test within the past 18 months was also abnormal, obtain records to verify, and if
 no colposcopic examination has been performed during the past 18 months, referral for
 colposcopy may be indicated especially if her age is greater than 25 and her pap testing

compliance has been erratic.

- If the client has been treated for high grade cervical dysplasia in the past (cryocautery, LEEP, or cone biopsy), then referral for colposcopy evaluation is probably indicated and if possible with the provider who performed the treatment in the past.
- If an HPV test result is available and the woman is negative for oncogenic HPV types then a
 pap in 1 year is appropriate in most situations. If the woman was positive for oncogenic HPV
 then referral for colposcopy is indicated if abnormal cytology. A recent consensus panel
 concluded that in women with a normal cervical cytology result but positive for oncogenic HPV
 have a low risk of HGSIL and can be managed with repeat cytology in 6 months (Obstet
 Gynecol 2004; 103: 304-9).
- If a woman is HIV positive or immunosuppressed she needs colposcopy to evaluate any abnormal cytology.
- Consult the Family Planning Medical Director if the decision is not clear as each patient's individual history may bear on the decision to refer for colposcopy.

High Grade Squamous Intraepithelial Lesions (HSIL or CIN II/III)
Or Carcinoma In-Situ (CIS) or Invasive Cervical Cancer Suspected
Atypical Squamous Cells Indeterminate for Dysplasia (ASCUS) High Grade also termed by the new Bethesda System as ASCUS cannot rule out HSIL

These diagnoses require immediate referral for colposcopy and biopsy. Remember cytology specimens are only estimates of biopsy pathology and final diagnosis may be milder or more severe. CIS or carcinoma-in-situ is also called Severe Dysplasia or CIN III. CIS is not invasive cervical cancer, but it is associated with a high rate of progression (20% to 30% over 10 years) to invasion so it should be treated, however, CIN I or even CIN II can have a 60-80% spontaneous regression rate and are often not treated unless it persists for more than 2 years.

Abnormal Glandular Cells

Women with pap test results in this category usually need endometrial biopsy, endocervical curettage and colposcopic examination. Most cervical cancers are of squamous cell origin, but 10-15% of cervical cancers originate from the glandular epithelium. Unfortunately, adenocarcinoma is more likely to missed on routine pap test and has a more aggressive course.

- Atypical Glandular Cells of Undetermined Significance (AGCUS) Refer for ECC and colposcopy. There is a very high rate of severe dysplasia or even cancer with this cytology result and the client needs further evaluation.
- Endocervical Dysplasia or Adenocarcinoma, Atypical Endometrial Cells or Adenocarcinoma: These women need immediate referral for endocervical curettage and colposcopy as they have a high likelihood of needing treatment. There is no longer a reactive atypia type of AGCUS with the new Bethesda System and any glandular atypia or dysplasia should be investigated.

Other Indications for Referral for Colposcopic Evaluation

• Following hysterectomy, if there are any abnormal cells, even just atypia, this woman needs referral for colposcopy and evaluation.

- If there is a visible or palpable lesion of concern to the provider.
- Unexplained, persistent vaginal bleeding, especially postcoital bleeding, can be a symptom of cervical cancer and may require colposcopy and ECC.

Colposcopy

Referral for colposcopy should be done using the consult and referral guidelines. You may use the Colposcopy Patient Handout. The PHSKC Family Planning Program may perform some of the colposcopy evaluations if the individual provider has been formally trained and works under the supervision of the Family Planning Medical Director. The procedure for colposcopy involves visualization of the cervix with the colposcope, application of 5% acetic acid solution, examination of the entire squamo-column junction, biopsy collection if indicated, silver nitrate application or Monsel's Solution for bleeding, and if necessary endocervical curettage (ECC). Use the Informed Consent For Colposcopy Form, Colposcopy Report, and the Colposcopy Log to document the consent, visit, and track the results and for review with the Family Planning Medical Director if a question.

If the biopsy result is CIN II or III, label the chart with a <u>Do Not Purge Sticker</u> to prevent the destruction of the chart. There can be treatment of cervical dysplasia by cryotherapy by trained providers if the case was reviewed by the Family Planning Medical Director. Use the <u>Cryotherapy Patient Handout.</u>

Cryotherapy visits involve obtaining consent using the <u>Informed Consent for Cryotherapy</u>, verifying pregnancy is absent, use of a cryoprobe with lubricating jelly adequate to cover the ectocervical lesion, turn on the refrigerant and perform two 3-minute freeze – thaw cycles or time needed to freeze 5 mm past the lesion. Women over the age of 35, or with a history of prior cervical dysplasia treatment, CIS or glandular dysplasia should obtain their colposcopy evaluations with providers that will be able to offer excisional treatment. When referring for colposcopy because of persistent ASCUS or LGSIL changes, make sure the cytology result is current. If it has been more than 16 weeks, the pap test should be repeated, as these changes may have resolved or worsened. If the pap is then normal, the client probably does not need colposcopy, but consult with the Family Planning Medical Director.

Endometrial Biopsy

If a patient needs an endometrial biopsy use the <u>EMB Procedure Form</u> and <u>EMB Consent Form</u>. These procedure should only be done within the family planning program under the direction of the Family Planning Medical Director because these patients are referred and will likely need evaluation and treatment outside the program's scope of practice.

Colposcopy Services for Minors

Since no other provider in the county will perform colposcopy without money and parental involvement, the PHSKC Family Planning Program may offer a limited service to minors as part of our contraception and STD services. For all of 1995, there was only one woman under 18 with a CIN III pap in the PHSKC program. For all the Planned Parenthood clinics in the USA over a 5-year period of time, there was a single invasive cervical cancer in a teenager, a 19 year old with abnormal cytology prior to diagnosis.

Post-Colposcopy Complications

Rarely a client will present after colposcopy with complaints of bleeding following the cervical biopsy. Perform a speculum exam and if the biopsy site is actively bleeding, apply silver nitrate or Monsel's solution, along with pressure for 3 to 5 minutes. If the bleeding cannot be controlled,

refer the client to an emergency room or gynecology clinic for electrocautery or suture. Clients are told to avoid vaginal penetration for 3 to 7 days following cervical biopsy.

Patient Education about Dysplasia and HPV

There is a lot of controversy, but some studies have suggested that tobacco use promotes and/or prolongs the HPV dysplastic effect on cervical epithelium. It is also unproven but believed by some, that women with high folate levels may have less cancer. Foods that contain high levels of folate are dark leafy greens, nuts, eggs, and meat. We know dysplasia is caused by HPV infection and the best protection is no genital contact with an infected person. Patients may be given the Information About the HPV Infection Patient Handout. Condoms have not been shown to significantly prevent HPV infection. Also HPV infection detection by pap test may be years after initial infection so it is usually impossible to pinpoint the source. In managed care systems, provision of an HPV test on a liquid cytology sample with an ASCUS result could identify women needing colposcopy rather than repeating the cytology test which will also identify women needing colposcopy. Because HPV type testing has no other benefit at this time, we do not offer HPV testing but a woman can seek this FDA approved test (Hybrid Capture II) from other local providers. A recent consensus panel concluded that in women with a normal cervical cytology result but positive for oncogenic HPV have a low risk of HGSIL and can be managed with repeat cytology in 6 months (Obstet Gynecol 2004; 103: 304-9).

Follow-Up After Cervical Dysplasia Treatment

If cryocautery, laser, LEEP, or surgical knife cone was performed, then confirm the tissue diagnosis by obtaining the pathology and operative reports. This is to make sure there was no invasive cervical cancer present, because if there was invasive cancer then this client needs to be referred back for further treatment and/or cancer follow-up. Cancer follow-up is individualized and can involve multiple visits and imaging tests. If the pathology specimen confirms dysplasia only, then repeat the pap test six months after the procedure and then every 6 months for two years from the date of the treatment. The <u>Post Cervical Dysplasia Treatment Tracking Alert Slip</u> can be used to flag the chart. If the pap test shows evidence of dysplasia, refer back to the treating provider for colposcopy.

Follow-Up After Colposcopy When No Treatment Done

REMEMBER, CIN I is not treated and CIN II might not be treated. A pap test in one year from the colposcopy is all that is needed. Refer back for colposcopy at that time, if the 12 month pap result is abnormal, even an ASCUS, because HGSIL may have developed and treatment may now be considered depending on the individual's history.

PAPNET Referral

If the woman requests her negative or normal pap test to be reviewed by the PAPNET system, then call the cytology lab to arrange this. For 1997 the patient had to write a 50-dollar check that was attached to the cytology requisition. The regular cytology fee is still charged. The local cytology lab will then send on the test to PAPNET after their review. If the pap test is abnormal then it cannot be sent to PAPNET. This automated system's only purpose is to re-screen negative test to see if they can detect any abnormal cells.

Low Income Colposcopy Referrals With No Insurance

 Harborview Medical Center Women's Clinic (206-731-3367, 325 Ninth Ave.) accepts all women, no pre-payment, sliding scale for all costs form women who qualify as low income allowance.
 Payment plans possible. Every Thursday morning. See the <u>Information About Referral to</u> Harborview Medical Center handout for more information.

- Swedish Family Medicine (206-386-6111 (press 1), 1401 Madison) can see women every
 Thursday morning and Friday afternoon. This is Family Medicine not Gynecology consult. The
 woman is responsible for costs of anesthesia and lab including the colposcopy biopsy costs of
 \$200 to \$300 they may be able to get it "written off" or forgiven but this requires "proof of
 income".
- Community Health Care Clinics in Pierce County (253-589-7030, 9112 Lakewood Dr. S.W., Tacoma) offers colposcopy, no client refused. All visits pay \$10 and there is a sliding scale with proof of income. The most client ever pays is \$80. They will directly schedule the colposcopy if the client brings her records.
- Community Health Care Clinics in Pierce County (253-597-3813, 1002 South "I" Street, corner of 11th and "I" in downtown Tacoma) does colposcopy every day. They require an initial visit to review records before the colposcopy visit. They also offer a sliding fee with proof of income.

ysfunctional Uterine Bleeding

Definitions

Menorrhagia >7 days or 80mL Metrorrhagia – irregular intervals Menometrorrhagia – irregular and excessive

Differential Diagnosis of Abnormal Genital Bleeding

- Pregnancy
- Cancer
- Infections; endometritis, cervicitis
- Anatomic cause; fibroids, polyps, bleeding from other sites (anus or urinary tract)
- Systemic; thyroid, drugs, hormones, bleeding disorders, herbs

Dysfunctional uterine bleeding is common in teenagers for the first two years after menarche due to immature pituitary-ovarian axis function. In perimenopausal women it is also common, usually due to ovarian failure. In women, aged 20 to 40, polycystic ovary syndrome (PCOS) can present with obesity, hirsutism, ovarian cysts, and infertility, in addition to irregular menses. All of these women tend to have anovulatory cycles. A cycle with no ovulation produces no progestin withdrawal, hence abnormal menstrual shedding.

Physical exam should include an assessment for the following:

- Cervix erosion, lesion, polyp, infection
- Uterus size, shape, contour
- Adnexa size
- Thyroid enlargement

Diagnosis

Diagnosis includes a history of bleeding pattern, duration of the problem (menstrual calendar for past year), number of days bleeding monthly, regularity (cyclic versus intermenstrual bleeding) and amount (number of pads/tampons on heaviest day). Tests for infection and a pap smear for cervical cancer should be done. Hematocrit should always be done. UCG may be considered as ectopic pregnancy and threatened spontaneous abortion commonly present as menorrhagia rather than amenorrhea. Women over age 40 with intermenstrual bleeding should be referred for an endometrial biopsy especially of their cycles do not respond to therapy. Screen for hypothyroid symptoms and consider a TSH if indicated.

Management

If the bleeding is severe and the hematocrit under 30 or hemoglobin under 11, evaluate for postural hypotension. Check BP supine and then when standing. A significant drop of BP or severe anemia (hematocrit <26) is usually an indication for hospitalization. A positive HCG or other evidence of a complication of pregnancy usually requires emergent referral to a gynecologist or an emergency room.

If very heavy, prolonged bleeding, an estrogen-containing OCP taper can be used. Administer up to 200μg EE a day (Nordette 1 to 2 pills TID) until the bleeding slows, then give 1 to 2 pills BID until the bleeding stops, and then finish the pill package. This will usually stop the bleeding in two or three days. Warn women that the bleeding after they stop the pills will be heavy because the thick, overgrown lining accumulates due to her unopposed estrogen and using progestins will cause a "medical D&C." Give her a **Menstrual Calendar Reminder Card (front / back)** to document the days and amount of bleeding.

Women with PCOS usually should continue with low dose oral contraceptives until they are ready to seek a pregnancy. The OCP can prevent ovarian and uterine cancer and reduce their circulating androgens. Perimenopausal women may continue OCPs until age 50 if they have no other risk factors.

Women who are not currently bleeding heavily may be started any combination monophasic pill to regulate bleeding. Women who do not need contraception and do not want to take oral contraceptives, which is the preferred treatment, may be managed with cyclic oral medroxyprogesterone (Provera) 10 mg daily for 10 days each cycle starting on day 15 of cycle or if not cycling can give day 1-10 of every month, for three months. If more than three months, this should be provided by the primary care provider because on-going Provera is more costly than OCPs and it is not a contraceptive method, hence not part of the Family Planning Program. Women seeking to get pregnant should be advised that once the bleeding begins (and lasts 24 hours) on the Provera they could stop taking it as long as they took at least 5 days of the Provera.

Women who do not respond (decreased bleeding and stop intermenstrual bleeding) after three to six months of treatment should be referred as they may require imaging, hysterosalpingography, or hysteroscopy to rule out endometrial polyps, submucous fibroids, adenomyosis, and other pathological conditions. Any women over age 40 whose bleeding does not respond after three months of hormonal management should be referred for evaluation and an endometrial biopsy if one has not already been done. If an endometrial biopsy is done, the EMB Procedure Form and EMB Consent Form need to be used. The risk for endometrial cancer is elevated in obese women, and if they have a history of PCOS or are nulliparous, this can further increase their risk.

ysmenorrhea

Diagnosis

Dysmenorrhea is defined as cyclic pain, headaches, or bloating with menstruation. Chronic pelvic pain is present when pain is persistent for more than three months. Many women with pelvic pain also have dysmenorrhea. The <u>Pelvic Symptom Diary</u> may be helpful to document more details regarding the pain.

Treatment

Hormonal contraceptives, which inhibit ovulation and endometrial proliferation, can significantly decrease dysmenorrhea and PMS.

Dysmenorrhea is usually caused by prostaglandin production and the most effective treatment is taking a NSAIDS medication on the very first day of the menses before prostaglandin production has peaked. Prostaglandins are produced as progesterone levels drop which destabilizes the endometrial lining and cellular membranes degenerate releasing prostaglandins. Use of the Lng IUS or synthetic progestins (COC pills, progestinonly methods like Norplant, DMPA or pills) can all decrease the amount of endometrial proliferation hence less tissue to slough with a menses.

- For pain, suggest aspirin or 200 to 400mg ibuprofen (available without prescription) first. If severe, can prescribe:
 - Ibuprofen 400 or 600 mg #40, one every six to eight hours; Start before or at onset of menstrual pain, limit to 20 pills each month, refill for one year. Also, Naproxen 500 mg bid #20 can be used, at or before onset of menstrual pain for five days.
- For severe bloating and heavy achy discomfort, prescribe (through outside pharmacy): Hydrochlorothiazide 50 mg #30, one-half to one in the morning for three to five days before each menses. Refill once only the first year.
- For premenstrual depression could try: Pyridoxine (B₆) 25 to 50 mg. daily starting seven days before each menses.
- Consider continuous or extended COC pill use if symptoms persist on cyclic OCPs.
- If chronic pelvic or abdominal pain, the <u>Bowel Program Handout</u> and the <u>Are You Getting Enough Fiber? Handout</u> may be helpful.
- If chronic bladder pain, the <u>Bladder Discomfort Program Handout</u> and the <u>Bladder</u> Health Handout may be helpful.

nfertility

Definition

Infertility is when a couple cannot conceive after one year of unprotected sex. Primary infertility means the woman or man has never been pregnant or fathered a pregnancy. Secondary infertility is when a pregnancy was possible in the past. The causes of infertility are multiple, approximately 35% of infertility is due to tubal factor, 35% male factor, 10% cervical factor, 10% unknown, and only 10% are due to ovulation difficulties amenable to clomid type therapies. As women age, their risk for infertility increases. At age 24, women have the greatest rate of successful pregnancy and women after age 35 with infertility often will require specialty services. After age 35 about 30% of women will not be able to have a successful pregnancy and this increases to 60% after age 40 (Fertility Sterility 2002; 78:215-19). As part of aging the risk for a miscarriage increases as well to 25% after age 35. The risk of a genetic abnormality is rare in women under 30 (1/500), and increases with age to 1/270 after 30, and 1/60 at age 40. Pregnancy related mortality also increases in older women (Obstet Gynecol 2003; 102:1015-21). In summary, women should be counseled that the very best age for pregnancy for good maternal and child outcome is age 24 and waiting until one is over 30 is not the best strategy.

Program Goals

According to the Title X guidelines, there are three levels of infertility service and these are quoted below:

Level I:

Initial infertility interview, education, examination, appropriate laboratory testing (hemoglobin or hematocrit, pap smear, and culture for gonorrhea), counseling and appropriate referral.

Level II:

Includes semen analysis, assessment or ovulatory function through basal body temperature and/or endometrial biopsy, and postcoital testing.

Level III:

More sophisticated and complex than level I and II services.

Title X sites must include Level I services and these are currently being done by the family planning practice guidelines under routine history and physical exam services. We believe Level 3 services are best provided in the context of an infertility service with ultrasound monitoring and referrals can be made to Harborview for clomid or other workup. Until society agrees to subsidize infertility services, we will not be able to supply much assistance since most successful treatments, like IVF, are not available without money.

Procedures

In addition, providers may offer:

- Basal Body Temperature education using the <u>Basal Body Temperature Chart</u>, which is very similar to the Natural Family Planning section in the guidelines, and charting to confirm biphasic = ovulatory.
- **Semen Analysis** referral if indicated (no proven recent male fertility). Provide the client with the <u>Semen Analysis Information Handout</u>.

- Postcoital Testing is possible, which is essentially a wet mount test combined with a
 cervical mucous evaluation for estrogen effect done 2 days before anticipated ovulation
 date and within 9 to 12 hours after intercourse. The slide should then be evaluated for
 motile sperm. If at least one forward moving sperm is seen on the whole slide, they have
 a 50% chance of pregnancy over the coming year compared to only 15% if no sperm or
 only immotile sperm are found.
- Referral to HMC for hysterosalpingogram can be recommended, which can be done by referral.
- Strongly advise both partners to quit all tobacco use. Smoking not only leads to erectile
 dysfunction and poor sperm quality but also has been linked to female infertility and
 miscarriage (Lancet 2004; 363: 628).

A possible scenario would be a baseline evaluation to collect three months of basal body charts, refer for semen analysis if no prior fathered children, perform a postcoital test with the third cycle to document mid-cycle estrogen mucous and motile sperm, and then refer for hysterosalpingogram if no pregnancy after one year of unprotected intercourse and with biphasic temperatures on the basal body charts.

enstrual Suppression or Withdrawal Bleeding Manipulation

Overview

Contraceptive hormones that block ovulation can also be used to suppress bleeding. DMPA with long-term use will result in amenorrhea in 90% of women by 2 years of use but during the first year only 50% have amenorrhea and women can have very heavy irregular bleeding. When women on DMPA are finally amenorrheric it is because of hypoestrogenism. Ovarian suppression without exogenous estrogen results in a low estrogen state consequently these women get amenorrhea but also have a loss of bone density. For this reason, if a woman is specifically requesting menstrual suppression the use of a combination product may be prudent, if estrogen can be used.

For **skipping a single period**, any OCP can be used simply by skipping the period week pills and going directly to another pill package, so a total of 6 weeks of the hormonal pills are taken followed by the usual pill free or period week. Advise women that spotting might happen but typically it is light and painless and it is important to keep taking the pill to maintain contraceptive efficacy. Multiphasic pills are more likely to trigger bleeding and it is possible taking the second package backwards to create at least 2 weeks of the same dose pill might help although it is not proven. It might be best to advise women wishing to skip just one period to use a monophasic pill but if this is not practical even a multiphasic pill will work most times.

For **extended cycles** (skipping some periods), a monophasic 30 mcg EE_2 and norgestrel pill has been shown to be effective for skipping every other month period (42/7 cycle). Seasonale is a brand name for a pill (30 mcg EE_2 and 150 mcg Lng) taken for 84/7 days with a 7 day period or a 91 day cycle. There was a lot of irregular bleeding (not just spotting) even at the end of the year and a pulmonary embolus reported in 1 of the approximately 450 users. For this reason, women seriously interested in decreased periods should be encouraged to consider continuous use of lower estrogen dose pills instead of longer cycles for both safety (decreased dose exposure) and less irregular bleeding.

For **continuous active pill use**, a monophasic 20 mcg EE₂ and 100 mcg levonorgestrel pill, has been shown to be effective with 80% of women by 6 months only having rare bleeding. During the first 6 months irregular bleeding is very common and worse than with cyclic use. Missed or late pills can trigger the bleeding. If still bleeding at 3-6 months, consider a switch to NETA progestin pill but with only 20 mg EE₂ dose, without a period week.

Skipping the pill free week results in 7 more days each cycle of hormone pills and no week to allow the pill hormones to drop to zero. This prevents hormone withdrawal symptoms like bleeding, headaches, and mood changes. But it is also likely that there can be a small net increase in overall hormone exposure. A single study of only 30 women suggested the SHBG and HDL levels were slightly higher in women with extended 42 day cycles using a 30 mcg EE₂ pill. For this reason, extended cycles should be restricted to 30 mcg or less EE₂ dose and continuous or daily use to 20 mcg EE₂ formulations.

The patch delivers an estrogen dose equivalent to an oral 30-35 mcg EE₂ pill and should not be used until studied closely for daily use or no periods. It could possibly result in hyperplasia or excess estrogen effects. Phasic formulations increase the risk of irregular bleeding and are not appropriate for extended or continuous use. All sub 50 mcg extended OCP cycle literature has been

with gonane type progestin products and it is probable that for good endometrial stability a long half-life gonane type progestin is effective. However, norethindrone 20 mcg EE₂ products have a high rate of missed or silent menses with cyclic use and appears to work well especially in older women with less ovarian activity and perhaps the weaker progestin triggers less bleeding. Do not use desogestrel progestin products for continuous use, this progestin doubles the risk of blood clots in cyclic users and it is possible if this would increase with daily use (American Journal Obstet Gynecol 2004; 190:332-7).

Although, the CVR (vaginal ring) does contain a metabolite of this desogestrel progestin, the ethinyl estradiol serum levels are so low with the CVR it is likely the estrogen exposure would be lower than with 20 mcg oral pill use. Extended or continuous CVR use can suppress withdrawal bleeding. The levels of hormones released by the CVR stay high enough to block ovulation for up to 5 weeks (35 days) of use, but it is best to go no longer than 1 month of use per ring. Insert a new ring on a set day like the 1st of each month to take out old ring and insert a new ring. If the woman notices a lot of spotting at the end of each month, changing to a new ring sooner (by 4 weeks) may help. It is likely just as with continuous pill use irregular bleeding will be common in the first 6 months and it should decrease although there are no published studies.

For women wanting to do menstrual suppression or skip periods on the OCP or the CVR the following should be done:

- 1. Counsel and document the reason the woman is choosing this schedule (i.e. withdrawal symptoms, headaches, wants no period, wants better OC efficacy, etc.) and that she is aware this is not FDA approved. Long term studies have not been done but it is unlikely there would be any additional risk especially if doses used are less than cyclic OCs (cyclic 30 mcg EE₂ pills actually deliver more estrogen than daily 20 mcg EE₂ pills). Remember to discuss alternative choices like LngIUS or DMPA although the LngIUS does not suppress ovulation in at least half of women and DMPA can result in hypoestrogenism.
- 2. Write prescription for hormone pills only, skip spacer pills, #84 with 4 refills for 1 year. Give her a menstrual diary to record all bleeding and counsel carefully to expect irregular bleeding (can be 3 weeks of daily bleeding of 1 to 2 pads) and the relationship to pill taking compliance.
- 3. A year of continuous OCP prescription requires 18 pill packages. A year of extended or 42 day cycles requires 15 pill packages. It is best to only dispense 3 to 4 months prescription until well established use. Give the client a <u>Menstrual Diary</u> to record bleeding sometimes by looking at the actual days it is reassuring and trends can then be seen.
- 4. The woman should be strongly counseled that irregular bleeding is common and to be expected in the first 6 months. Use the Continuous OC Handout.
- 5. See client at 2 to 3 months for blood pressure, menstrual diary and symptom review.
- 6. If at 6 months persistent irregular bleeding consider pregnancy testing, infection testing, referral for an ultrasound to rule out fibroids, and consult family planning medical director.
- 7. Offer HCG testing when amenorrhea if missed pills or concerns and prudent to do HCG testing at first revisit.
- 8. After 2 years of no bleeding, screen for polycythemia or hemochromatosis (a rare genetic disease causing excess iron absorption) by checking hemoglobin. If hemoglobin level is 15 or

greater, check a complete blood count, a fasting ferritin and transferrin saturation and if abnormal (ferritin >300ng/ml or transferrin saturation >45%) or if a family history then consult the Family Planning Medical Director before initiating or continuing suppression. Strongly consider referral to UW Iron Overload Clinic at 206-598-4886. The treatment for hemochromatosis is to avoid iron excess, which can lead to damaged organs (liver, brain) and while a woman could still choose menstrual suppression, she would need hematocrit monitoring and possibly phlebotomy with her primary provider. Polycythemia, excess red cell mass, can increase blood viscosity and the risk for thrombosis. Usually this happens because of renal or pulmonary disease or rarely a genetic condition (polycythemia vera) with abnormal myleoproliferation. These patients would need referral, probable phlebotomy, and menstrual suppression should only be done with very close monitoring.

Last updated: 6.03.04

Continuous Birth Control Pill Use

Taking an active, hormone containing, pill every day is designed to stop all bleeding after an initial period of irregular bleeding. This handout explains how and gives tips to decrease the irregular bleeding.

Why do the spacer pills cause the uterus to bleed?

"The Period Pills," "spacer," "or "sugar" pills contain no active or hormone medication. The reason you bleed when you take spacer pills is because your hormone levels drop. You bleed because you did not take a progestin hormone or "real" birth control pill. The lining of the uterus needs stable hormone levels to prevent bleeding. The best way to prevent any bleeding or spotting is to have constant levels of the estrogen and the progesterone hormones, because these hormones support and keep the blood lining of the uterus stabilized.

What do birth control pills do to the uterus?

Birth control pills work to shrink the blood lining of the uterus. Over time the lining is so thin, the chances of unexpected bleeding and spotting become very low. It is very, very unlikely something is building up inside your uterus when you are on the pill. As a matter of fact, the risk of endometrial cancer decreases by 80% in women using the birth control pill for five years.

Irregular Bleeding is common at first

Break-through bleeding, or bleeding when you are not scheduled to bleed, is very common in the first 6 months of continuous birth control pill use. Your body is getting used to the constant level of hormones. If you have been on a higher dose pill or injection contraceptives, it can take longer to stop irregular bleeding. Spotting is when the amount of blood is so tiny that no pad or tampon is needed. The longer you take the continuous pills the less bleeding and spotting will happen. You do not need to stop the pill to have a period because bleeding happens, instead try to figure out what caused the bleeding and keep taking the daily pill if you want to have no bleeding. Stopping the pill only begins the whole process again.

How can you help prevent a drop in the pill hormones and stop bleeding/spotting?

The most important thing is to take your pill as close as possible to the **same time every day.**Estrogen in the body begins to wear off, especially if you take your pill over 4 hours late.

Other suggestions if spotting continues:

All these suggestions and ideas listed below are to help you make it through the first six months of continuous pill use. Most women will have significantly less bleeding or spotting after six months. Keep a menstrual diary so you can learn what triggers a bleeding episode for you. Remember all women are individuals. You can learn about how you metabolize your pill and what works with your body.

Alcohol: Drinking alcohol keeps your liver busy detoxifying the alcohol so your hormone levels, especially estrogen, can be higher for a few days. If you drink everyday, even a glass of wine, your body could be used to the alcohol, so if you stop drinking, your estrogen levels may drop and trigger spotting.
Tobacco: Smoking can increase your metabolism of estrogen and result in lower levels of estrogen. If you smoke you now have another reason to quit or at least greatly reduce the amount you smoke

Last updated: 6.03.04

	Other medications: Many medications, for example antibiotics, antifungals, anticonvulsants, and even herbal drugs like St. John's Wort, can change the amount of the pill hormones absorbed by the stomach and the metabolism of these hormones. It is very common to have some spotting with a new medication or a change in dose of medication. Sometimes these medications can actually decrease the pill hormones so much they become less effective at preventing pregnancy. Therefore, it is important to tell your provider about all the medications you are taking.
	Time of day and stress can affect your hormone levels. The progesterone receptors in the uterus look a little like cortisol receptors, so it might be possible that increased stress can trigger a change in progesterone activity. Taking the pill at night , before bed, could make the hormones peak when the cortisol levels are at nighttime levels and this could affect the activity of the hormones. Also, at night, the pill does not have to compete with food in you stomach to be absorbed. So, if you are having persistent spotting you could try switching the time of day you take your pill. However, you can expect some initial spotting with any change in the usual time you take your pill and it may take two weeks for your body to equilibrate to the new pill taking time.
	Diarrhea or vomiting: Anything that makes the pill go through your system too fast can make the pill not work as well because it was not absorbed or, worse, if it is lost in the vomit.
	Altitude: Some women report spotting when they take airplane trips or climb mountains. It could be the change in air pressure, just going to a new time zone, or even a change in your sleep patterns. If travelling in a different time zone, you should attempt to take your pill at the time based on your normal time zone.
	Non-steroidal anti-inflammatory medications, like Naprosyn, Aspirin, or Ibuprofen can decrease period bleeding and menstrual cramps, because they lessen the chemicals that cause period bleeding and decrease irritation in the lining of the uterus. Stop using them when your spotting stops. If your spotting continues after one week, you should call your provider, you may need a higher dose and your provider can give you a prescription. You should not use these drugs for more than 1-2 weeks or they could hurt your liver or kidneys.
	Vitamin C , 1000 mg, taken with your pill can help increase estrogen absorption for some women, so you should try this if the spotting has gone on for more than five days. However, you should stop taking the high dose of Vitamin C either when the spotting stops, or after a week if the spotting hasn't stopped. If you take it for too long, your body gets used to that large amount of Vitamin C, so that if you don't take it, you will then have a drop in estrogen levels and start spotting again!
	Grapefruit juice contains a chemical that slows estrogen metabolism if the pill is taken with a glass of juice. More estrogen may be available to your body to stop the spotting.
If y	ou have any questions about any of these suggestions, please call your clinic. Often your

with permission.

provider can help and may even need to do an exam to find out why you are bleeding because there may be an infection or change in health that is causing the bleeding. **Please call your clinic before you stop the birth control pill.** This handout is from the www.noperiod.com website and is used

reconceptional Management

All women who can become pregnant and who present for continuing care in primary care settings, family planning clinics, and other women's health care settings are candidates for preconception care.

The period of embryogenesis and greatest risk to fetus starts before the missed menses and continue until the 4th or 5th month of pregnancy when most organ development is complete. Provision of preventive education and care can help increase the health of a pregnancy or future pregnancies. The Pregnancy Form should be used if pregnancy testing is the main purpose of the visit. The Before You Get Pregnant: Planning is the Key handout can be provided to the patient. The following preconception assessment and counseling points should be offered as appropriate.

Risk Assessment

- Individual conditions age less than 18 years or over 34 years, nutrition, exercise, education, stress level, partner support, support system.
- Social conditions economic status, housing, social support, family violence.
- Adverse health behaviors tobacco, alcohol, illicit drug abuse.
- Immunizations rubella immunity, hepatitis risk
- Medical conditions infections, prescription and OTC medications; or chronic medical conditions such as diabetes, epilepsy, hypertension, heart disease, renal disease, and autoimmune disease (lupus, rheumatoid arthritis).
- Gynecologic history fertility problems, endometriosis, abnormal Pap smears, STD, sexual practices
- Prior obstetric history recent delivery, infant weight over 9 pounds or under 5.5 pounds, five or more pregnancies, three or more miscarriages, two or more abortions after 14 weeks, or adverse outcome of pregnancy.
- Family history Sickle cell or other hemoglobinopathies, Tay-Sachs disease, cystic fibrosis, mental retardation, seizure disorders, birth defects, diabetes, bleeding disorders.
- Environmental conditions work place hazards, toxic chemicals, radiation.
- Barriers to family planning, prenatal care and primary health care.
- Neural tube defects if at risk for this (self, prior history, family history, anti-seizure medication use, or any other low folate condition), they need to take 4 mg orally every day of folate, preferably beginning 3 months before conception and throughout the pregnancy. This dose is not available in a prenatal vitamin and needs to be supplied separately as an outside prescription.

Medical Evaluation

- Physical examination Document weight and blood pressure.
- Laboratory testing Do hematocrit or hemoglobin and Pap smear. If status is unknown recommend rubella immunization if known no pregnancy at time of vaccine and hepatitis B (HBsAg) testing or immunization.

- High-risk women should be screened for gonorrhea, chlamydia, syphilis serology, and HIV.
- Refer for genetics evaluation and counseling as appropriate.

Health Promotion

Promotion of healthy behaviors: Counsel about proper nutrition including vitamins, diet counseling, and food programs. Women should take 0.4mg (we prescribe 0.8mg as part of a prenatal vitamin) folic acid daily for three months before seeking pregnancy. An over the counter prenatal vitamin will have 0.4mg of folate. Stress avoidance of and treatment of smoking, alcohol, illicit drugs, and teratogens, and practice of "safer sex" with new or casual partners. If not already done, advise women to be immunized for rubella and hepatitis B. Counsel about availability of social, financial, and vocational assistant programs.

To avoid heavy metals like mercury, the US FDA is recommending that pregnant women, women who may become pregnant, and lactating women avoid shark, swordfish, king mackerel, and tilefish along with recommending these women eat less than 12 ounces a week of other fish and less than 6 ounces if the seafood or fish is caught locally by the woman or family. www.epa.gov/ost/fish

Pregnancy spacing should be at least two years and not more than 9 years between children. Advise women to continue family planning until a pregnancy is planned. When discontinuing hormone contraceptives, use barrier contraception for one cycle to avoid a theoretical but unproved risk of increased loss of implantation with atrophied endometrium. After DMPA use, expect a delay of six to eighteen months before conception. After IUD use, either copper or Lng IUS, use barrier contraception until after one menses. With barrier contraception there is no need to delay pregnancy. Menstrual calendar recording is important during the time from cessation of contraception until a pregnancy is diagnosed.

Counsel women about early prenatal care and high-risk programs if warranted. Advise women over age 34 of amniocentesis if birth is expected after age 35. Identify barriers to care and offer assistance to overcome them. Refer them to a primary care provider for treatment of medical conditions including changes in medication if appropriate and for good control of conditions that adversely affect pregnancy. Refer to high-risk pregnancy programs.

Reduce psychosocial risks by counseling or referral as appropriate to home health agencies, community mental health centers, safe shelters, medical assistance, housing assistance, or social support.

Advise women to return for pregnancy detection promptly for a delayed menses or for symptoms of pregnancy so that prenatal care can be started early in pregnancy.

Paternity testing is offered by a private company, DNA diagnostics Center at 1-800-DNA-Center (1-800-362-2368) but it can be very expensive (cash needed), invasive (requires amniocentesis while pregnant), and requires samples from the possible father.

regnancy Detection

Procedure

The <u>Pregnancy Screening Form</u> is used for history collection and visit documentation. The <u>Pregnancy Screening Form Instructions for Completion</u> are detailed instructions for RN/CSO staff. Complete initial/annual exam is encouraged and should be done when appropriate/possible.

Exam

A weight and blood pressure should be done. Pelvic examination and inspection for signs of cervicitis with GC culture, chlamydia culture and Pap smear as appropriate should be done for women who have a positive pregnancy test and:

- are less than age 24 or meet STD guidelines for CT screening
- · are seeking abortion or are undecided regarding their decision
- have conflicting dates
- have symptoms of infection
- have history suggestive of ectopic pregnancy (pain, bleeding, etc.).

Also, on exam confirm uterine enlargement. The uterine size can correlate with EGA as follows (Obstet Gynecol 2001; 98: 341-4):

- 7 weeks = tangerine
- 8 weeks = juice orange
- 10 weeks = naval orange
- 12 weeks = grapefruit
- 20 weeks = to umbilicus

Lab

HCG (human choriogonadotropin) is made by the pituitary by all women and even men at very low levels but during pregnancy the trophoblast or placenta makes large amounts of HCG. A website detailing the history of pregnancy testing is located at http://www.history.nih.gov/exhibits/thinblueline/. A urine pregnancy test can be done for HCG to confirm pregnancy, unless pregnancy is detected by abdominal examination. A qualitative serum pregnancy test is rarely indicated but can be done in the clinic using the same pregnancy test kit as used for urine. The urine HCG may be a false negative if the urine is very dilute or if the HCG level is low. Rarely the urine test may turn faintly positive after the 3 minutes wait. If a test is negative but a pregnancy suspected, repeating the test after 48 hours may be advised or collecting a quantitative serum test to send to a lab.

There can also be a false positive serum HCG test with a negative urine test because the patient's serum, an antibody or protein, reacts with the test reagent but HCG is not present.(Am J Obstet Gynecol 2002; 187: 217-24). Both urine and serum HCG tests sensitive to 25 mlU remain positive for about six weeks after induced abortion. By contrast they are often negative at the time of a spontaneous abortion since the serum HCG levels can be so low with abnormal pregnancies. A serum HCG level of 1500mlU or greater

indicates the pregnancy should be visualized as intrauterine by vaginal ultrasound. Most normal pregnancies double their HCG level every 48 hours early in pregnancy (before 10 weeks). If there was a recent abortion or a reason to suspect the test is only positive because of a recently ended pregnancy then a consider quantitative test or a repeat test in 2 weeks to document a fall in the level to negative.

Management

If the pregnancy test is negative and the woman is seeking pregnancy:

- Consult with client regarding plans and options. Consult the Preconception guidelines.
 Repeat the test in two weeks if no menses still, then do a complete exam if not already done.
- Counsel or refer to infertility and preconception guidelines if the couple has been actively trying to achieve a pregnancy for over one year.

If the pregnancy test is negative and the woman is not seeking pregnancy:

- Provide interim contraception; consider Emergency Contraception if appropriate; consult regarding contraceptive choice and usage.
- Repeat test in two weeks if still no menses, and do a complete exam if not already done.

If the pregnancy test is positive and indicating on going pregnancy provide counseling regarding all options (provide the <u>Pregnancy Options Handout</u> and <u>Abortion Facts Handout</u> if needed) and refer as appropriate for:

- abortion
- adoption arrangements
- clinic prenatal care
- DSHS complete referral if indicated
- maternity screening
- private physician prenatal care
- WIC

For all women, complete the pregnancy verification section of the <u>Pregnancy Screening</u> <u>Form</u>.

Tell the client to take the confirmation letter to the DSHS Community Service Office closest to her current mailing address and make an application for financial assistance. Give the client the instruction sheet on what information to take with her. Provide the additional copy of the form for her to give to her provider if appropriate.

When the client receives her medical coupons, ask that she bring a coupon to the Health Department. This coupon can be sent in or given to the family planning, family health, or adolescent clinic, a WIC visit, maternity screening appointment, or a prenatal visit within the Health Department.

Discuss screening for rubella serology, HIV, syphilis, and HBsAg as part of routine prenatal testing and encourage the client to obtain counseling and testing as soon as possible.

Discuss asymptomatic STDs, risks to the woman and fetus/neonate, and encourage clients not getting a pelvic exam to return to the clinic for screening or obtain screening from her prenatal provider as soon as possible.

Spontaneous Miscarriage

A spontaneous abortion (SAB) is an involuntary loss of an embryo or fetus before 20 weeks of pregnancy. Approximately 50 to 75% of all pregnancies end in spontaneous abortion, however, most occur at about the time of implantation and thus the menses is not significantly changed and the pregnancy and subsequent abortion are not recognized clinically. Hence, only 15 to 20% of clinically recognized pregnancies are lost. About 50% of SABs after six weeks are due to a chromosomal abnormality of the pregnancy. Serious illness, some viral infections, or toxic drugs in the mother may also be a cause. Women reporting 3 or more SABs should be referred to an obstetrical provider to be assessed for reasons for recurrent miscarriage like autoimmune disease, uterine anomaly, or genetic abnormality. If the client is a PHSKC obstetrical patient and presents with SAB, the obstetrical guidelines need to be consulted.

Diagnosis

The pregnancy test may be positive if the tissue passed recently and it is possible it can take up to 4 weeks to clear the HCG to a negative urine test. It is important to make sure the HCG levels do not persist as this could be a sign of gestational trophoblastic disease or another pregnancy. The uterus may be small for dates. Symptoms of pregnancy (breast tenderness, nausea) may have disappeared. Vaginal bleeding with or without cramps indicates that spontaneous abortion is possible, although 25% of pregnancies that go to term had some spotting during the pregnancy. Perform an exam to rule out infection or other cause of bleeding, to determine if the cervical os is dilated, and to date the gestation. Do a hematocrit or hemoglobin as appropriate. Refer for Rh typing if not known because Rhogam is indicated if the client is Rh negative. Referral will be needed to administer the Rhogam because the Family Planning program does not stock this. If a Doppler monitor is available you may try to listen for fetal heart sounds.

Ectopic gestation should always be suspected with pain, bleeding, and early pregnancy. One out every 50 pregnancies in the United States is an ectopic pregnancy. Prior history of ectopic pregnancy, PID, or current use of an IUD, sterilization, or contraceptive implant can all increase the risk of ectopic pregnancy. Refer emergently to a facility with diagnostic imaging and gynecology services if an ectopic pregnancy is suspected. Ectopic pregnancies can be treated medically if diagnosed early.

Management

If a nonviable pregnancy is suspected before the onset of bleeding and cramping, refer the client to her pregnancy care provider for management. The clinician managing the pregnancy may order serial quantitative serum pregnancy tests to determine if an abortion is inevitable or an ultrasound to identify gestational dating and viability.

There is no evidence that medical intervention can change the miscarriage process. Often gestations before 6 weeks or greater than 11 weeks will need a procedure to complete the abortion. Most abortions between 7 to 10 weeks pass without surgery. Discuss the possibility of a miscarriage. Advise resting, staying near home, use of NSAIDs, and avoiding sexual intercourse or anything in the vagina until the process has resolved. If bleeding and cramping occur or tissue passes, advise the client to see her primary care provider or go to an emergency room if the bleeding is greater than one pad an hour for over three hours. Often the bleeding and cramping

Last updated: 12.20.04

resolve after the tissue has passed. All clients with bleeding should be assessed and counseled regarding the possibilities of ectopic gestation. Consult the PHSKC Maternity Practice Guidelines for the management of threatened spontaneous abortion and suspected ectopic pregnancy.

Remember ovulation is not suppressed by HCG and can happen even with a positive urine HCG test as early as 10-14 days following a miscarriage, so women at risk for pregnancy need counseling and provision of contraception.

ermination of Pregnancy

Evaluation

Management after a spontaneous abortion or an induced abortion is similar. After a woman has had a termination of a pregnancy, a surgery like D&C, or a suction curettage for a spontaneous abortion, usually she should continue under the care of the physician or abortion provider until resolution of all problems has occurred. Bleeding with clots similar to or lighter than a normal menses is expected. If the woman did not have suction curettage after a spontaneous abortion, the bleeding may be heavier. Women frequently have some cramping or discomfort for several days. Breast tenderness and other symptoms of pregnancy may continue for a week or so.

The pregnancy test may remain positive for 4 weeks after an induced abortion because the HCG is a protein which can be at very high levels in the first trimester of pregnancy and although the level drops rapidly immediately after tissue is passed for from abortion, it can take weeks for complete renal clearance to a negative test level. It is important to remember that HCG does not block ovulation (at least at low levels) and women can ovulate even with a positive HCG test, hence women at risk for pregnancy still need access to ECP and contraception. If a patient has had unprotected intercourse and has a positive pregnancy test with a recent abortion, consider the possibility of a new pregnancy, gestational trophoblastic disease, or just normal decline of HCG levels by counseling the woman appropriately and have her sign the Specific Informed Consent Form to document she knows to get a repeat test.

Management

It is important to refer the woman to the abortion provider for complications as they may need to repeat the procedure and the follow-up is included in the cost of the abortion. If the procedure was done elsewhere or after a spontaneous abortion without medical intervention, a woman should be seen in the clinic for post-abortion care. Call and ask to speak to the abortion provider if necessary to arrange the referral.

For cramping and bleeding, suggest ibuprofen or similar medication. Rest, application of a heating pad to the abdomen, and massage of the abdomen may help. For heavy bleeding with pain, perform an exam and evaluate for infection and consider antiobiotics as for PID and/or methergine. If the infection is severe refer to emergency room for possible IV antiobiotics.

If there is active bleeding or cramping, the uterus is soft and enlarged, the cervix has dilated, or there is tissue visible in the cervical os, immediately refer the client to a physician or emergency room. Sometimes a suction dilatation and curettage is necessary to completely evacuate the uterus. Prompt management is needed if there is tachycardia or signs of hemorrhage or infection.

If tissue has passed, the bleeding and cramping have subsided, the uterus is contracted, firm and normal size, and the cervix is closed, the abortion is probably complete. The client may return home. She should avoid intercourse or anything in the vagina for about 10 to 14 days. Stress that if increased bleeding and cramping recur, she should immediately see a physician or go to an emergency room. Address contraception as indicated. Often the delay of a contraception method only exposes the woman to another pregnancy because ovulation can

occur as soon as two weeks after termination. About two weeks after an abortion the woman should be examined for evidence of infection or remaining products of conception. If the examination is normal, discuss future plans and provide contraception as appropriate. All hormonal contraceptive methods can be initiated on the day of the abortion and often this is advised. Any woman with a history of irregular bleeding following termination that persists beyond four weeks should be carefully evaluated to insure there is not retained tissue, persistent HCG indicative of a gestational troproblastic malignancy, infection, or other pathology.